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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
3713405-01017

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/799,299	March 12, 2004

First Named Inventor
Gerald Horn

Art Unit	Examiner
3761	Melanie Jo Hand

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 46,541.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

Thomas C. Basso
Typed or printed name

312-807-4310
Telephone number

June 29, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Gerald Horn
Appl. No.: 10/799,299
Conf. No.: 7833
Filed: March 12, 2004
Title: NIGHT VISION COMPOSITION
Art Unit: 3761
Examiner: Melanie Jo Hand
Docket No.: 3713405-1017

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF

Sir:

The Pre-Appeal Brief is submitted in reply to the Final Office Action dated December 31, 2010 (Final Office Action). This Pre-Appeal Brief is filed contemporaneously with a "Pre-Appeal Brief Request for Review" and a "Notice of Appeal."

The Pre-Appeal Brief, Notice of Appeal, and Pre-Appeal Brief Request for Review are submitted in response to the rejections of Claims 33-36 as maintained in the Final Office Action. Claims 33-36 are pending in this application. Claims 33-36 were rejected under 35 U.S.C. §103 in view of US5252295 (Gluchowski) and US5236904 (Gerstenberg). Applicant asserts that the Patent Office's rejections in the Final Office Action rise to the level of clear error and make the case proper for pre-appeal review.

Of claims 33-36, claim 33 is the sole independent claim. Claim 33 recites an ophthalmic formulation in aqueous solution for topical administration including a sterile aqueous carrier; and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. Claims 34-36 depend from claim 33.

Even assuming that the references are properly combinable, Applicant believes that the alleged combined teachings fail to teach or suggest the claimed invention. As previously discussed, the claimed invention is directed to an ophthalmic formulation in aqueous solution for

topical administration with an active phentolamine compound that can effectively reduce pupil size in dim light to improve vision in dim light and further minimize redness in the eye upon use. Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, Published Specification (US2004/0176408), Examples 1 and 2 and Tables 1 and 2, beginning on page 6. Moreover, such unexpected results are further supported by an Affidavit of Gerald Horn, M.D. that was previously submitted in this case.

At the outset, the Patent Office even admits that the primary Gluchowski reference "does not teach a pharmaceutically active compound consisting essentially of phentolamine." See, Final Office Action, page 3. At best, Gluchowski indicates that oxazoline or imidazoline compounds are preferred (See, Gluchowski, col. 3, lines 39-41), but nowhere does Gluchowski specify an ophthalmic formulation that includes a pharmaceutically active compound consisting essentially of phentolamine and in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness as required by the claimed invention. Therefore, Gluchowski on its own is distinguished from the claimed invention.

Further, the Patent Office cannot rely solely on the secondary reference (Gerstenberg), if at all, to remedy the deficiencies of Gluchowski. At the outset, Gerstenberg is directed to a different application that requires a different type of formulation via a different route of administration, e.g., treatment of sexual dysfunction via injection of a peptide N-terminal histidine C-terminal methionine amide. See, Gerstenberg Abstract. Clearly, Gerstenberg fails to describe a phentolamine-based ophthalmic formulation in aqueous solution for topical administration that can effectively reduce pupil size in dim light to improve vision as claimed, let alone recognize the unexpected benefit of phentolamine in an ophthalmic formulation as Applicant has demonstrated. Indeed, Gerstenberg is not relevant prior art given that it is not even directed to an ophthalmic formulation. Therefore, Gerstenberg fails to cure the deficiencies of Gluchowski.

Moreover, the Patent Office has continued to improperly rely on Applicant's alleged admission (see, Final Office Action, page 3) to fill in the gap between the subject matter as claimed and as disclosed in the cited references. Clearly, this reliance on Applicant's alleged

admission is an example of improper hindsight as a basis to justify the combination/modification of the references in the first place. Again, Applicant has demonstrated the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations, clearly unrecognized by the cited references.

In contrast, Gluchowski is directed to intraocular pressure and not reduction in pupil size, let alone the reduction of pupil size in dim light to improve vision in dim light where redness is further minimized as required by the claimed invention. Indeed, Gerstenberg does not relate to ophthalmic formulations. Therefore, Applicant believes that the cited references fail to render obvious the claimed invention, even if properly combinable, and thus respectfully request that the rejection be withdrawn at least in view of same.

In light of the above, Applicant respectfully submits that the obvious rejection of Claims 33-36 is improper and should be reversed. Accordingly, Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any additional fees are due in connection with this application as a whole, the Commissioner is authorized to deduct such fees from deposit account no. 02-1818.

Respectfully submitted,

K&L GATES LLP

BY _____

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Date: June 29, 2010